(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
14 June 2001 (14.06.2001)

PCT

(10) International Publication Number
WO 01/41664 A1

(51) International Patent Classification[7]: A61B 18/02

(21) International Application Number: PCT/US00/32796

(22) International Filing Date: 4 December 2000 (04.12.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/457,958 9 December 1999 (09.12.1999) US

(71) Applicant: CRYOCATH TECHNOLOGIES, INC. [CA/CA]; 16771 Chemin Ste-Marine, Kirkland, Quebec H9H 5H3 (CA).

(71) Applicant and
(72) Inventor: CARROLL, Sean [US/CA]; 199 Hampshire Road, Beaconsfield, Quebec H9W 3N8 (CA).

(72) Inventors: WITTENBERGER, Dan; 4806 Lucerne, Pierrefonds, Quebec H8Y 2E2 (CA). SANTOIANNI, Domenic; 4 Edison, Kirkland, Quebec H9H 5B2 (CA). ABBOUD, Marwan; 18501 Antoine-Faucon, Pierrefonds, Quebec H9K 1M7 (CA). AUBERT, Mathieu-Philippe; 1360 rue Guertin, Saint-Laurent, Quebec H4L 4B9 (CA).

(74) Agent: CHRISTOPHER, John; Gunster, Yoakley & Stewart, P.A., Suite 1400, 500 East Broward Boulevard, Fort Lauderdale, FL 33394 (US).

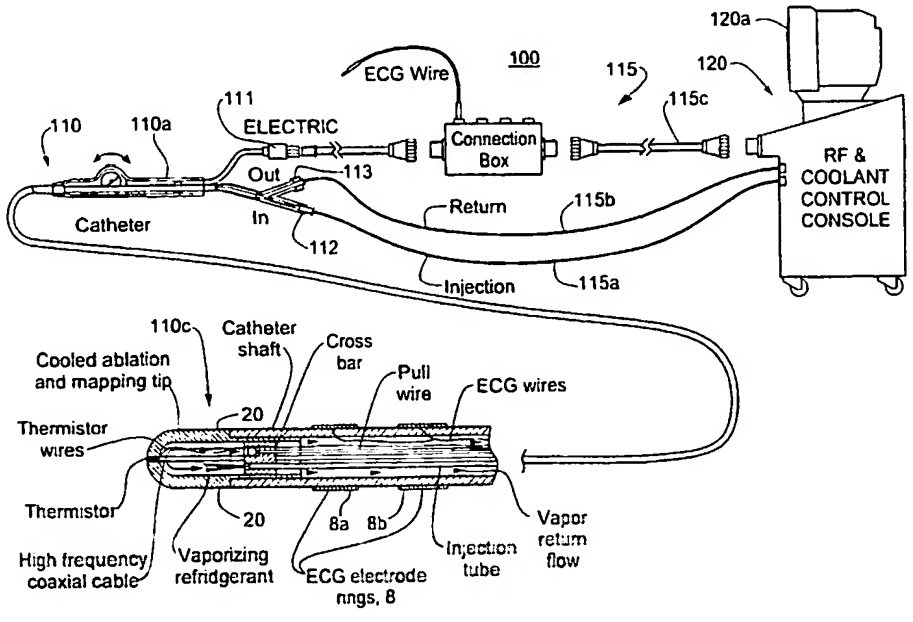
(81) Designated State (national): CA.

(84) Designated States (regional): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

Published:
— With international search report.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: CATHETER WITH CRYOGENIC AND ELECTRICAL HEATING ABLATION



(57) Abstract: A catheter (110) for the cryotreatment of tissue includes a catheter body (110b) and a treatment (110c) tip positioned at the distal end of the catheter body. The treatment tip has a cooling segment operable at a temperature sufficient to freeze tissue and an electrically-driven ablation assembly operable to apply heating ablation energy to the tissue. The cooling segment has a thermally conductive wall for contacting and thermally treating tissue in contact with the thermally conductive wall. The cooling segment and the electrically-driven heating ablation are controlable to effect tissue ablation.

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freezing lesions may take longer to generate, allowing the operator to terminate the ablation to avoid adverse effects, and the lesions may be of lesser extent, so that they heal more quickly. These factors may dictate choosing a cryoablation catheter when the treatment sites are located in a thin cardiac wall. For open surgery the particular limitations or benefits of one or the other catheter may be addressed by special constructions, such as providing two-sided tissue contacting plates for cooling or for providing RF energy through the target tissue. However, for endovascular use each type of catheter remains subject to distinct limitations.

Cryocatheters may be adapted for endovascular insertion, or for insertion along relatively confined pathways, for example through a body lumen, or through a small incision to and around intervening organs, to reach an intended ablation site. As such, they are characterized by a relatively elongated body through which the cooling fluid must circulate, and a tip or distal end portion where the cooling is to be applied. The requirement that the coolant be localized in its activity poses stringent constraints on a working device. For example when the catheter contact must chill tissue to below freezing, the coolant itself must attain a substantially lower temperature. Furthermore the rate of cooling is limited by the ability to supply a sufficient mass flow of coolant and to circulate it through the active contact region, and the efficacy of the contact region itself is further limited by geometry and physical properties that affect its ability to conduct heat into the tissue. The rate of cooling may change depending upon the effectiveness of thermal contact, e.g. upon the contact area and contact pressure between the catheter and the tissue, and may be further influenced by ice accumulations or other artifacts or changes due to the freezing process itself. Moreover, it is a matter of some concern that proximal, adjacent or unintended tissue sites should not be exposed to harmful cryogenic conditions. These somewhat conflicting requirements make the actual implementation of an effective cryocatheter complex. One such device treats or achieves a relatively high rate of heat transfer

technology, cooling fluid may also be applied to prevent excessive heating of the electrode itself, or to chill tissue and allow cold-mapping during a treatment regimen. Other special constructions such as the use of an electrically conductive saline irrigant, may be used to extend the size of the lesion, and cardiac signal sensing electrodes may also be spaced along the length of the tip, allowing a single instrument to detect and map cardiac signals during treatment. However, RF catheters typically operate quite locally. Resistive tissue heating falls off with the fourth power of distance, and while electrode cooling may somewhat change their heating characteristics, their limited range of operation often necessitates lengthy treatment procedures involving many iterations of cold mapping, ablative lesion forming, and re-mapping or checking steps. The necessary number of steps may require over an hour to perform.

Accordingly, there remains a need for a catheter construction that achieves an extended range of thermal transfer.

There is also a need for a cryocatheter construction that ablates tissue more effectively, or to a greater depth.

There is also a need for a cryocatheter construction that is controllable to provide uniform and repeatable thermal treatment over a wider range of thermal energy transfer conditions.

SUMMARY OF THE INVENTION

One or more of these and other desirable features are achieved in a catheter that includes a treatment segment with both heating and cryoablation elements and a controller that operates both these sets of elements to control the extent of the ablation lesion. The catheter may, for example, be a modified phase-change cryocatheter with a tip through which a controllably injected phase change coolant circulates to lower the tip temperature, and also possessing an RF electrode assembly. The cryogenic and RF supplies are operated in coordination to set a tip

through a cryogenic ice ball, the catheter may extend the depth and width of the region of active ablation, allowing a small endovascular catheter to create larger ablations in a controlled manner. The cryocatheter may be fitted with a bipolar RF ablation electrode assembly positioned to facilitate lesion placement.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

Figure 1 shows a first embodiment of a cryoablation RF catheter and system of the present invention;

Figure 2 shows representative RF (including microwave) and thermal conduction temperature profiles;

Figure 2A illustrates thermal conduction and RF treatment regions with overlaid profiles;

Figure 3 shows a combined ablation of the invention; and

Figure 4 shows one operating method of the control console.

DETAILED DESCRIPTION

Figure 1 shows a first embodiment of a cryogenic treatment system 100 of the present invention and illustrative elements thereof. System 100 includes a treatment catheter 110 having a handle 110a, and elongated cryogen transporting body 110b and a catheter tip 110c. The catheter 110 is connected by various conduits or cables to a console 120 which may, for example, have a display monitor 120a and other data entry or display accessories such as a keyboard, a printer and the like. The console 120 is connected to the catheter by various lines 115 which may include a coolant injection line 115a, a coolant return line 115b, and electrical cabling 115c which includes an RF drive line and may further carry console control outputs such as valve or switching signals, and outputs of various

(Figure 1) are also shown in or on the catheter tip for performing thermal sensing and tissue impedance or conduction signal monitoring functions.

The foregoing description describes a catheter system in general terms with a cryogenic cooling mechanism and an RF electrode assembly as well as several sensing elements useful in such a system. Preferably in this cryoablation system a phase change coolant is injected through the injection tube 1 to vaporize and expand at the tip of the catheter, and return via a vacuum or suction passage to the return connection 113 at the catheter handle. Also the phase change material is preferably provided at ambient temperature but relatively high pressure through the handle and body 110a, 110b of the catheter, such that cooling only occurs upon release of pressure and expansion within the chamber at the tip of the catheter. Cooling operation of this device involves controlling the timing and amount of coolant injected through the injection tube 1 at the injection pressure, which may, for example, be a pressure of about 400 psig. The entire catheter may be dimensioned for endovascular deployment to fit through a No. 9 French introducer or smaller, and attain a catheter tip temperature down to about -70°C. In its cooling aspects the tip acts on surrounding tissue by thermally conductive contact. In addition, the RF heating of the tip 20 allows operation of the catheter to heat surrounding tissue with an energy profile that is different from and independent of the cooling profile of the catheter tip. The RF energy may heat tissue to temperatures of +70°C or more, and it operates with a different mechanism and heat generation profile than the thermal conduction profile of the cooler. The controller operates these two systems, in various treatment regimens of the invention described further below, to condition and treat tissue in the same procedure, which may for example, effect mapping or ablation; position or shape the treatment region; extend the reach of ablation treatment; or reduce the time required between steps of a multi-step ablation or combined ablation/mapping operation.

electrode contact surface, and remains extremely hot to a somewhat greater depth, then drops quickly with increasing depth. It will be appreciated by those skilled in the art that the term "RF" as used in this context customarily refers to an AC signal of a suitably high frequency (typically over 30-50 kHz) so as to not introduce pain or muscle contractions, but that its typical mode of propagation is that of electrical conduction and resistive heating rather than electromagnetic wave propagation and attenuative absorption more typically associated with radio waves. As such, the rate at which RF energy delivers heat to tissue depends substantially on the impedance pathways to a distant ground electrode (for a monopolar device), or between electrodes of a bipolar device. Typically, heating drops with the fourth power of distance from the electrode, but the volume distribution profile may be improved with a broad surface electrode or larger catheter electrodes in the monopolar case, or by other means. Thus the RF heating profile in Figure 2 is intended as a representative profile but will be understood to vary, for example, with different electrode configurations, applied radio frequencies and average power levels, to influence the relative increase in heat, given the locally available heat conduction from blood circulation and other tissue-related physical parameters. In accordance with one aspect of the invention, the invention may include a hybrid RF cryocatheter with an exposed or projecting pair of electrodes tailored to produce a desired ablation lesion.

Finally, the third curve M in Figure 2 illustrates a typical profile for tissue heating with microwave energy. In this circumstance the applied energy has a microwave frequency, which may be selected, for example, so that its absorption coefficient in tissue depends substantially on factors other than electrical conductivity, such as the presence or concentration of hydroxyl groups or the like in the targeted tissue. In this case the energy applied and absorbed by tissue may drop off with a lower power function, so it has a more uniform profile extending at a depth into the tissue. The curve M accordingly may achieve a deeper lesion of

surrounding tissue at a defined depth, thus forming a self-limiting lesion of defined size.

To simplify the discussion herein, the term "RF ablation catheter" or the descriptor "RF" shall be used here and in the following claims to include microwave catheters and microwave signals in addition to the high frequency AC and radio frequency catheters and drive signals customarily denoted by those terms. It will be understood, however, that microwave catheters and microwave control consoles will have a distinct construction from devices employed at lower (non-microwave rf) frequencies, and the construction of hybrid cryo/microwave devices, while not specifically illustrated, will be understood to generally involve the incorporation of cryogenic cooling and control elements in a microwave device, with appropriate care to avoid adverse interactions of the two structures, such as microwave absorption by the coolant or antenna resonance effects of the metal components.

Continuing with a description of the operation of applicant's ablation procedures wherein the controller operates the two different types of ablation elements in a hybrid catheter, Figure 3 illustrates one such thermal profile of the present invention formed by overlaying a profile such as the cryotreatment curve of Figure 2 plotted as a dashed line below the nominal body temperature, and an RF profile such as the microwave curve M of Figure 2 plotted as a dashed line above normal temperature. As shown, the heating and cooling induced respectively by cryogenic thermal conduction and by the application of electromagnetic energy counterbalance each other in the near field so that the thermal profile remains always well within the damage threshold and no ablation occurs throughout the surface region A of tissue depth. In the intermediate depth region B where the magnitude of the cooling effect is smaller, the heating dominates, and tissue temperature rises above the damage threshold to produce ablation in a limited range or layer L of tissue located remotely from the catheter

effect of shifting the RF damage curve downwardly from the surface, or eliminating it in the near field. The RF energy, if applied for a longer time interval, may produce a lesion at depth, without damage to the surface tissue. The amount of applied surface cooling may be reduced, or terminated and the RF energy may also be applied for an even longer period to achieve the usual degree of ablation at the surface, but with tissue damage extending more deeply than is achieved with a pure RF ablation.

In another method of control, by operating the catheter to precondition or concurrently counteract the temperature of the tissue heated by RF, cold mapping may be carried out while the RF energy is being applied to tissue, thus simultaneously confirming a target site and reducing the sequential time intervals formerly required for mapping and ablation procedures.

The catheter may also be used to create cryogenic lesions, and, in other treatment regimens, the RF or microwave electrode is operated to preheat tissue, raise the tip temperature, or to warm tissue after cryoablation to allow signal mapping to be undertaken immediately. One particularly advantageous embodiment of this aspect of the invention employs a catheter which is operated as a drag line to lay down a linear lesion so that cooling and RF energy are both applied continuously as the tip is moved along the surface, for example, of an endocardial wall. The elongated chamber of the cardiac tip may operate with a relatively slow time constant to chill tissue along the intended path while mapping ahead of the RF electrode, and this electrode may then be actuated with a shorter time interval and/or higher power level to place lesions at an appropriate position in the endocardial wall, as determined by the previous mapping. Such operation is believed to be particularly advantageous for operations such as creating conduction blocks in complex cardiac pathways where deep or even external tissue (i.e. the exocardial wall surface) may be sustaining a reentrant arrhythmia.

extent, or proximity of a targeted triggering lesion or signal pathway, and may select an appropriate ablation cycle of the heating and cooling elements to most effectively ablate the particular target. One skilled in the art will appreciate further features and advantages of the invention based on the above-described embodiments, and, having described the invention, further variations and modifications within the spirit and scope of the invention will occur to those skilled in the art. Accordingly, the invention is not to be limited by what has been particularly shown and described, but is understood to be defined by the claims appended hereto and their equivalents.

5. The catheter of claim 1, wherein said electrically driven ablation assembly includes an electrode assembly for applying one of radio frequency and microwave energy.

6. The catheter of claim 5, comprising a driver configured to provide said one of radio frequency and microwave energy at a frequency effective to achieve enhanced absorption in said thermally treated tissue at a depth in said tissue.

7. The catheter of claim 5, wherein said driver is a microwave driver tuned for propagation through near tissue and preferential absorption beyond said near tissue to effect ablation at a depth within said tissue.

8. The catheter of claim 1, wherein said electrically-driven ablation assembly and said cooling segment are sequentially operable.

9. The catheter of claim 1, wherein said electrically-driven ablation assembly and said cooling segment are operable to selectively ablate tissue at a depth boundary of an ablation region.

10. The catheter of claim 1, wherein said electrically-driven ablation assembly and said cooling segment are operable to prevent near field charring or icing during ablation.

11. The catheter of claim 1, wherein said electrically-driven ablation assembly and said cooling segment are operable to maintain a non-ablating near field temperature while attaining an ablation temperature at a depth.

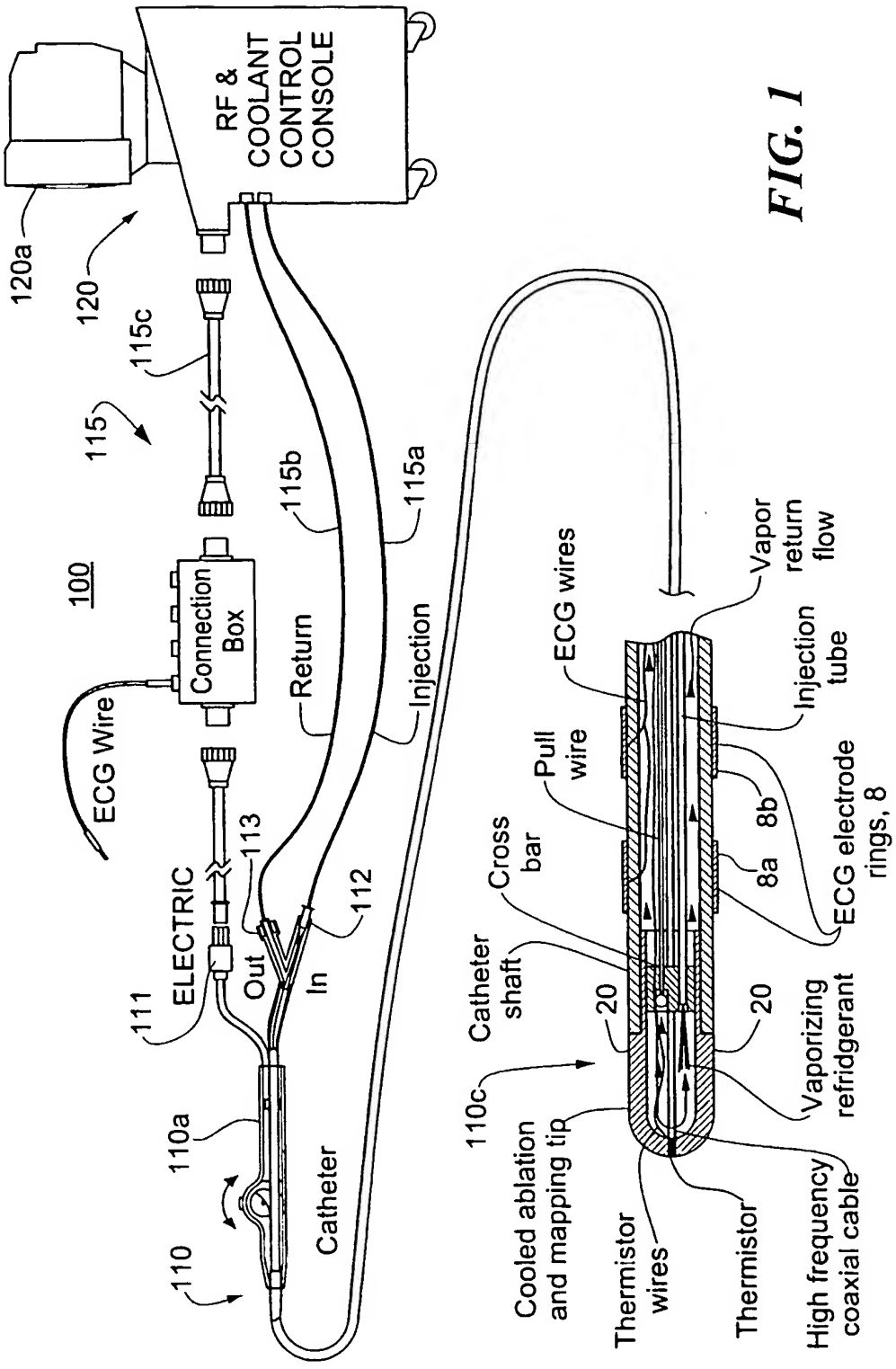
RF & COOLANT CONTROL CONSOLE
120a
120
115c
115
115b
115a
100
Connection Box
ECG Wire
Return
Injection
111
ELECTRIC
113
Out
In
112
110a
110
Catheter
Vapor return flow
ECG wires
Injection tube
Pull wire
Cross bar
8b
8a
ECG electrode rings, 8
Catheter shaft
20
20
110c
Cooled ablation and mapping tip
Vaporizing refridgerant
Thermistor wires
Thermistor
High frequency coaxial cable

FIG. 1

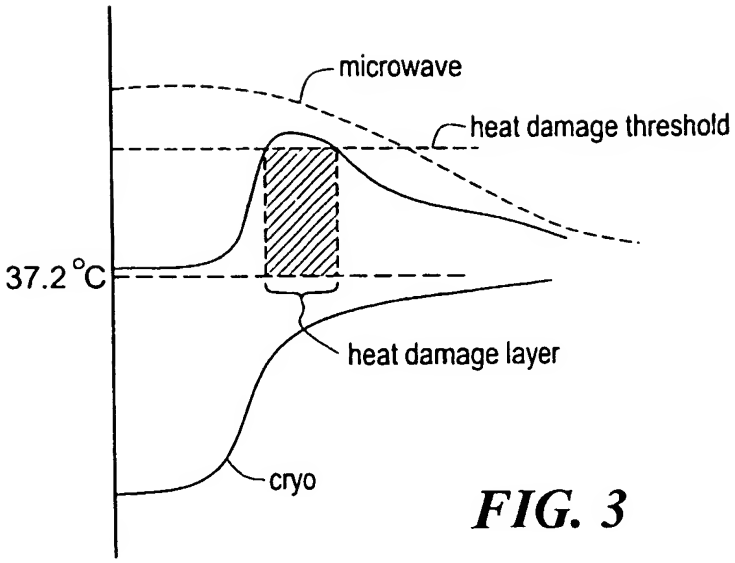
microwave
heat damage threshold
37.2 °C
heat damage layer
cryo

FIG. 3

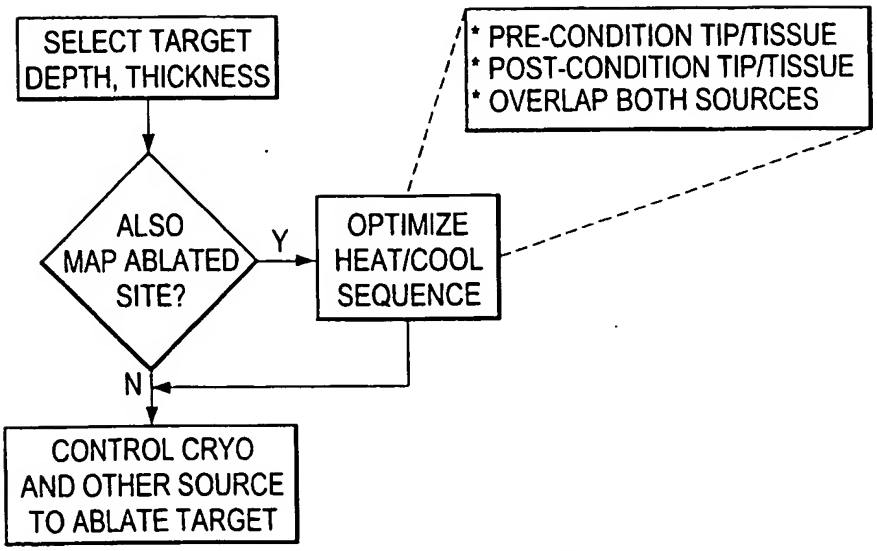
SELECT TARGET DEPTH, THICKNESS
ALSO MAP ABLATED SITE?
Y
N
OPTIMIZE HEAT/COOL SEQUENCE
* PRE-CONDITION TIP/TISSUE
* POST-CONDITION TIP/TISSUE
* OVERLAP BOTH SOURCES
CONTROL CRYO AND OTHER SOURCE TO ABLATE TARGET

FIG. 4

INTERNATIONAL SEARCH REPORT

Information on patent family members

Interna il Application No
PCT/US 00/32796

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